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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,417	08/08/2001	Azariah Jossifoff	6727/01367US	7902

7278 7590 07/18/2003

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EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/18/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,417

Applicant(s)

JOSSIOFF, AZARIAH

Examiner

Alton N. Pryor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 51-111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 52-54 and 100 is/are allowed.
- 6) ☐ Claim(s) 51,55,56,71,86-89,91-99,101-103,109-111 is/are rejected.
- 7) ☐ Claim(s) 57-70,72-85,90 and 104-108 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 71,91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 91 recites the broad recitation between about 6 and 10 wt % effervescent, and the claim also recites preferably about 8 wt % which is the narrower statement of the range/limitation.

Claim 71 is rejected for depending on cancelled claim 12.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 51,55,56,86-89,91-99,101-103,109-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roser et al (US 5958455; 9/28/99). Roser teaches an effervescent tablet that can comprise progesterone, trehalose (non-effervescent) and sodium carbonate and tartaric or citric acid (effervescent). See column 2, column 5 lines 11-23, column 11 lines 62-65, column 12 lines 4-13. Roser teaches that the tablet can be made in a variety of ways. For example, the tablet can be made by combining components in solution or suspension in an aqueous solvent to form a homogenous powder and then form tablets from the powder. In this version of preparation, excipients are added to the aqueous solvent or added to the powder. The active ingredient such as progesterone and trehalose are added to the solvent. See column 7 line 61 – column 8 line 15. Roser teaches several other ways to make the tablet. For example, another way is to combine trehalose, active, and excipients in the powder to form a homogeneous mixture and form tablets from the mixture. See column 8 lines 30-37. Roser also teaches another way to make the tablet involving mixing active solution with trehalose, drying the mixture and then subjecting the dried mixture to heat and vacuum prior to tablet formation. See column 8 lines 38-63. Roser does not teach using micronized progesterone and the exact ordering of steps of tablet formulation of the instant claims.

It would have been obvious to one having ordinary skill in the art to determine the

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optimum particle size of progesterone. One would have been motivated to do this in order to develop the most effective tablet for progesterone delivery to a female. It would have been obvious to one having ordinary skill in the art to have made the progesterone tablet by the instant method of preparation. One would have been motivated to do this

since Roser teaches that the tablet can be made by a number of processes which includes the preparation steps to the instant claims. In a claim to a preparation a change in the ordering of the steps are not significant without the support of unexpected results.

Allowable Subject Matter

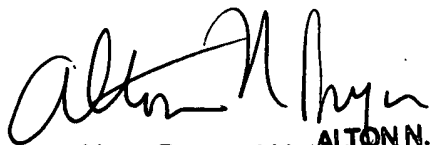
Claims 57-70,72-85,90,104-108 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 52-54,100 are allowable. The prior art does not teach or suggest the instant method wherein a lubricant is sieved. The prior art does not teach or suggest a method of placing in the vagina the instant progesterone tablet.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 703 308-4691. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. T. Page can be reached on 703-308-2729. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3592 for regular communications and 703-305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

A handwritten signature in black ink, appearing to read 'Alton N. Pryor', is written over the typed name and title.

Alton Pryor, AU 1616
July 16, 2003

ALTON N. PRYOR
PRIMARY EXAMINER